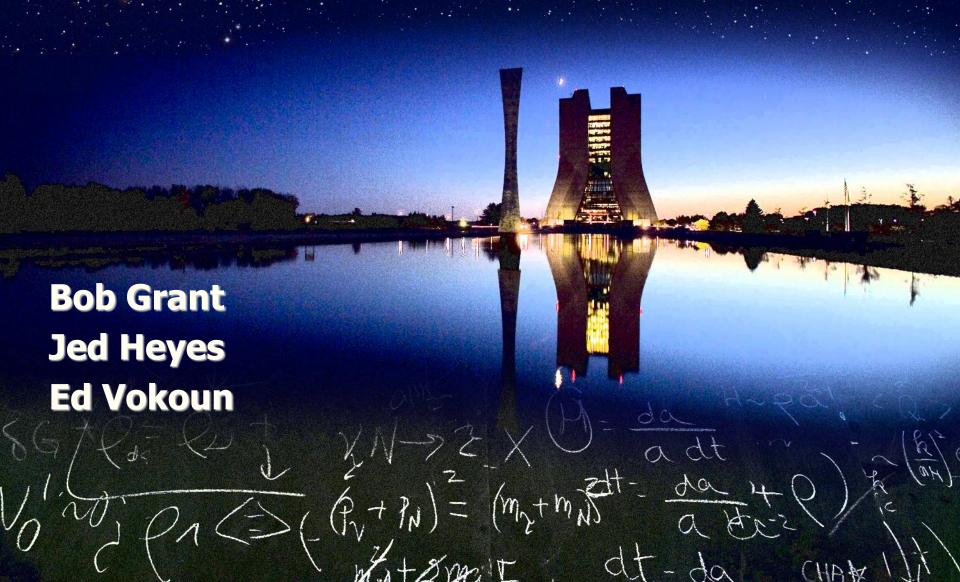
IQA & CA Implementation April 11, 2011



IQA Implementation

Quality Assurance Program Implementation



QA Implementation Activities

- Ongoing Communication Initiatives
- Scientific Research Projects
- Assessment Program
 - OQBP QA assessment schedule
 - Consolidated assessment schedule
 - Corrective Action Plan tracking
- Other activities & challenges



QA Implementation - Communication Initiatives

- Ongoing Communication
 - Weekly OQBP staff meetings
 - Ongoing implementation status, schedules, projects, issues, news
 - Fermilab Today QA related articles
 - National QA Day April fools April '09
 - Required IQA Training January '10
 - Lessons Learned Announcement Feature August '10
 - Murphy's Law September '10
 - Root Cause Analysis October '10
 - Lessons Learned "How To" November '10
 - Standard Processes January '11
 - Suspect/Counterfeit Items, S/CI February '11
 - Assessment Program April '11 . . . more through April '12



QA Implementation - Communication Initiatives continued

- Scheduling Meeting attendance, listening
- Assurance Council attendance, briefs as needed
 - QA implementation
 - Contractor Assurance
- ◆ ES&H/OQBP taskforce (harmonize FESHM & QA)
- Ad hoc briefs
- ◆ DOE FSO quarterly briefs since 2007 next April 11, 2011
 - QA implementation, status DOE QA CAPs



QA Implementation - Communication Initiatives continued

- ♦ D/S/C staff meetings & QAR support
 - QA Manager, QARs, QAEs, D/S/C staff
 - Mentoring, consulting, assistance with QAR related tasks
- ♦ QARs from each D/S/C active since 10/15/08 & OQBP QA staff
 - Weekly meetings
 - Implementation issues, lessons learned,
 - Assessments, changes in requirements (H13)
 - Reviews & critiques of new or changed QA documents, QA training
 - Assurance Council updates, D/S/C news etc
 - Status of CAPs



QA Implementation - Project QA Status

- Science / Project QA
 - Director approved project QA PM charge August '10
 - Future direction to be determined with the head of OPPS
 - Presentation on QA to management & project teams
 - Presented to head of OPPS, AD Research, AD Accelerator
 - Working with PPD QAR on QA Plans (Minerva, MicroBooNe & Mu2e)
 - Developing templates, make available to L1, L2 project managers
 - MicroBooNE Cryogenic Engineering QA Plan module, larger QA template
 - Draft QA in projects presentation for project teams
 - Attending PMGs, WGMs (APUL, DES, LBNE, NoVA, Project X, MicroBooNe & Mu2e)

Assessment Program Approach

- ♦ FY2010 process based D/S/C & OQBP selected assessments
- Current OQBP QA program 3 year approach
 - All organizations & processes to be assessed FY2011-FY2013
 - Against requirements identified in the IQA from DOE O 414.1C
 - Includes Scientific Research Projects in Fermilab Guidelines from ANSI Z1.13 (chosen from alternatives)
 - Priorities & sequence in the schedule
 - Outstanding CAPS (Inspection & Test)
 - Program Maturity (Records Mgmt, M&TE)
 - V&V
 - Risk
 - Emerging issues take precedence
 - Results of previous assessments



QA Implementation – Assessments, Schedule

- OQBP QA Assessments
 - ❖ FY2010 process based D/S/C & OQBP selected 6 small, 1 large (Power)
 - FY2011-2013 3 year approach
 - IQA criteria based, lab-wide
 - Includes scientific research, projects & support
 - Individual & summary roll up reports by criteria
 - FY2014 return to process based D/S/C & OQBP selected assessments
 - Most value to D/S/Cs
 - Most relevant QA criteria



3 Year OQBP Assessment Schedule

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Assessment Program - Fermilab Consolidated 3 Year Schedule

- Fermilab Consolidated Assessment 3 year schedule
 - All assessment types FY2010-FY2012
 - Meetings with D/S/C Heads for input, content
 - Categories of assessment types available to track
 - Management Assessments
 - Independent Assessments (OQBP, ES&H, Third-party such as DOE, ISO, etc)
 - Inspections (HPR, Walkthroughs etc)
 - Drills
 - Surveillances
 - Director's Assessments
 - Special Assessments (for cause)
 - ... Others mentioned in FAM Chapter 2 Appendix
- ♦ 2010 lists complete, maintenance ongoing, coordinating with QARs



QA Assessment Status

- OQBP Assessment Status at a Glance
 - ❖ FY2011 -
 - S/CI inspection & test all D/S/Cs Q1, Q2 individual reports complete, lab-wide roll up summary in progress
 - Scientific Tech Publ / editorial review Q1 report delivered
 - EVMS surveillance Q2 draft report in Fermilab review
 - Records management Q2, Q3 fieldwork in progress
 - OQBP V&V for closed assessment CAPs all D/S/Cs Q3
 - M&TE all D/S/Cs 2 Large x-cutting Q3, Q4



QA Assessment Results to Date

- OQBP Assessment FY2011 Results at a Glance
 - ❖ Inspection & test all D/S/Cs Q1, Q2 3 Findings
 - 2 segregation of nonconforming material
 - 1 inspection documentation
 - ❖ S/CI − 6 Findings
 - Not fully implemented (awareness, following procedures)
 - ❖ 17 Observations with recommendations for improvement
 - Documentation & records, infrastructure, work control, etc.



Science / Project QA Assessment Status

- Science / Project QA Assessments & Status
 - Science As-Is baseline final report delivered
 - AD for Research deciding path forward, gaps, CAPs
 - Program, & Projects (Minerva, MINOS, Muon Accelerator, D0, Lattice QCD)
 - Scientific Publication final report delivered
 - AD for Research deciding path forward, one CAP
 - 14% of publications assessed non-compliant
 - EVMS NoVA draft report in review at Fermilab
 - Final report to Head OQBP, Head OPMO, EVMS project 04/13/11
 - 8 CARs, 5 CIOs re EVMS & ANSI compliance



QA Implementation - CAPs

- Corrective & Preventive Action tracking
 - DOE 2006 QA assessment
 - DOE 2009 QA assessment
 - OQBP led assessments (includes 2009 As-Is)
 - Ad hoc tracking improvement initiatives (ex: training)



2009 DOE QA Concerns - CAP Status

- ♦ 4 New CAPs OQ-01/04/2010-01 thru -04
 - ❖ C1 & C2 Terms used in CAPA procedure OQ-01/04/2010-01 complete
 - ❖ C3 WSS/FESHM 1070 maintenance roles OQ-01/04/2010-03 complete
 - C6 Documentation of acceptance testing varies OQ-01/04/2010-04
 - Inspection assessment in progress final results 04/30/2011
 - ❖ C7 & C8 Identify assessment criteria, define terms OQ-01/04/2010-02
 - C7 FAM Mgmt. Assess. Procedure updated & posted complete
 - C8 Other FAM updates from 2009 assessment complete
 - Manual revised to incorporate H13 Clause requirements complete
 - Independent Assess. Procedure updated & posted complete
 - Lab-wide review (includes ES&H/OQBP taskforce) by 05/31/2011



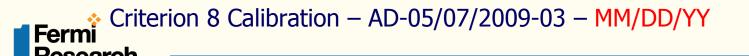
2009 DOE QA Concerns — CAP Status

- Existing As-Is CAPs
 - ❖ C5 Fermilab Chief Engineer OQ-05/22/2009-01 IQA being modified, Integrated into new Office of Program & Project Support (OPPS)
 - OQBP, OPMO, new Office of Integrated Planning (OIP)
 - Planning & support, EVMS, OHAP, Engineering Manual
 - C4 & SC1 (sig. concern) Inconsistent engineering practices, lack of Engineering Manual – OQ-05/22/2009-02 – complete
 - ❖ C9 & C10 S/CI roles & disposition OQ-05/30/2009-06 complete
 - Other activities
 - Collected training samples, S/CI Tags in inventory
 - FESHM update planned to reference the new tag
 - S/CI assessment along with Inspection & Test renewed awareness



2009 DOE QA Concerns — 4 CAPs from 2006 DOE QA assessment

- ❖ Criterion 2 Job specific training ITNAs OQ-08/10/2009-01 09/31/2011
 - Initial system enhancements & testing complete more in progress
- Criterion 4 Document management OQ-08/05/2009-01(a, b & c)
 - (a) EDMS (Teamcenter) est. completion 07/31/11
 - (b) CIO IT (Sharepoint) est. completion MM/DD/YY
 - (c) COO (policy, process) est. completion 07/31/11
- Criterion 4 Records management OQ-08/05/2009-02 complete
 - Handbook, procedures, training complete 01/19/10
 - Lab-wide assessment in progress summary rollup 07/15/11



IQA Implementation

Other QA Activities



QA Implementation – Other Activities

- Improved Integration with ES&H Management System
 - ES&H/OQBP task force (SSOs & QA Mgr)
 - Updating FESHM chapters & QA RCA & CAPA procedures
 - Next Fermilab Assessment Manual (FAM) by 06/30/11
- Improved S/CI Online Training tbd
- ♦ New Online Assessment Program Training in QAR review



IQA Implementation

Quality Assurance Program Challenges



QA Implementation - Challenges

- ♦ Software, frESHTRK versus Vector Reported to CIO -> Sharepoint?
 - Issue is resources
- Graded Approach
 - COO considering alternatives
- ♦ Timely implementation of CAPs from 2006, As-Is, 2009
- Maintenance of consolidated schedule
- Aggressive assessment schedule



QAEs

- FSO OQBP Joint Activities
 - Next quarterly IQA brief mid July 2011
 - ❖ Next FSO DOE QA assessment Q4 FY2012
 - Logistics, criteria, scope etc
 - Other meetings?



IQA Implementation

Questions?



CA Implementation

Contractor Assurance Implementation Status



Action Item			Total Basedadas	FY	10							FY	11					B-4
Number	Topic Name	Topic Description Number	Topic Description	Aug-10	Sep-1	Oct-10	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Dates
		1a	Contract mapping of SOW and Appendices/Clauses to DOE Orders and Director's Policies			mid												Aug 10 - mid Oct 10
		1b	Review initial contract mapping document (1a)			mid	mid									Р		mid Oct 10 - mid Nov 10
1	Contract Mapping		Map 1a, above, to programmatic documents (such as plans, manuals and procedures/implementing documents)								mid					E		Dec 10 - mid Mar 11
		1d	Create plan to fill gaps, if applicable								mid					E		mid Mar - Apr 11
		2 a	Identify management systems	Complete												R		
2	Management Systems	2b	Decide: Management System Ownership What documents need to be created to implement the Contractor Assurance System Format/Content of Programmatic Manuals/Documents							mid								Aug 10 - mid Feb 11
		2 c	Write Prime Contract Change Management Procedure							mid								Sep 10 - mid Feb 11
		2d	Write Manuals											mid		R		mid Feb - mid July 11
		За	Agree on:What is a policy?Levels of policies?		mid					mid						E		mid Sep 10 - Feb 11
3	Define New Policy Manual	3b	Agree on: What policies Fermilab will have Ownership						mid							v		mid Oct 10 - mid Feb 11
		3с	Establish document control protocols for policiesChange managementFormat of policies									mid				1		Feb 11 - mid Apr 11
4	Create New Policy Manual	4	Revise existing policies and write new policies as required											mid		E		Feb - mid July 11



CA Implementation Plan

Action Item				FY	10							FY	11					
Number	Topic Name	Topic Description Number	Topic Description	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Dates
	Management	5a	Draft Mgmt Review Procedure	mid				mid								w		TBD (Draft on hold)
5	Management Review Procedure	5b	Review & Approve Mgmt Rvw Procedure									mid						
6	Establish Board of Directors role	6	Establish Board of Directors role									mid						Dec 10 - mid Apr 11
7	Reporting and Metrics	7a	Establish reporting methods to the BoD									mid						
,	Reporting and Metrics	7b	Establish metrics for management systems															Apr 11 - May 11
		8a	Draft FICAP revision								mid	mid						mid Mar 11 - mid Apr 11
8	Revise FICAP	8b	Review & Approve FICAP									mid		mid				mid Apr 11 - mid Jun 11
		8c	Formalize worker feedback system (proceduralize)															TBD
9	Revise Comp Assessment	9	Revise Comprehensive Assessment Manual and schedule to accommodate changes in Contractor Assurance		Manual	Complete												TBD
		10a	Communicate CAS Program															Aug 10 - Aug 11
10	Communicate CAS to Fermilab	10b	Train Fermilab regarding CAS requirements						<u>:</u>					mid				mid Mar - Aug 11
		11a	Establish Benchmarking Requirements															Mar 11
11	Benchmarking	11b	Write Benchmarking Procedure							<u> </u>	mid		mid					mid Mar 11 - mid May 11
		11c	Implement benchmarking process										mid					mid May 11 - Aug 11
		12 a	Determine Graded Approach Methodology (plus test cases)							mid								Oct10 - mid Jan 11
12	Graded Approach	12b	Write Graded Approach Procedure															Feb 11 - March 11
		12c	Implement Graded Approach Procedure										mid					July 11 start
13	CAS Description	1 3 a	Determine CAS Description Approach															Nov 10
15	Cro Description	13b	Write CAS Description								mid							Dec 10 - mid Mar 11



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CA Implementation Plan - Status Overview

- Many items are late to start or overdue for completion.
 - Project management representative, COO, is aware.
 - Proposal for changing the implementation plan change and the approach to be taken were approved.
 - Targeting 04/17/11 for having a new schedule to COO
- Several items caused resources being applied to other things and the inability to access and work the issues with senior management.



- Contract Mapping
 - OQBP map contract of SOW and Appendices/Clauses to DOE Orders and Director's Policies
 - Complete
 - D/S/C to map above, to programmatic documents (such as plans, manuals and procedures/implementing documents)
 - Late: in progress
 - Create plan to fill gaps, if applicable
 - Late: awaiting D/S/C mapping



- Management Systems
 - Identify management system
 - Complete
 - Decide:
 - Management System Ownership
 - Late: awaiting Director Approval
 - Format/content of Programmatic Manuals/Documents
 - Late: draft in review
 - What documents need to be created to implement the Contractor Assurance System
 - Delayed: will wait until Program Manual format is decided and contract mapping are completed to be finalized



- Management Systems (Continued)
 - Write Prime Contract Change Management Procedure
 - Late: process diagram approved; need to create block diagram and procedure.
 - Write Manuals
 - Late: need to review a plan change proposal with COO
 - Note Entire plan will be re-planned. New schedule to be created.



- Define New Policy Manual
 - Agree on:
 - What is a policy?
 - Complete
 - Levels of policies?
 - Complete
 - Agree on:
 - What policies Fermilab will have
 - Late: Partial agreement on items proposed by OQBP; OQBP to work with MSOs. Need to complete D/S/C contract mapping to confirm
 - Ownership
 - Late: Proposal is awaiting completion of D/S/C contract mapping



- Define New Policy Manual (Continued)
 - Establish document control protocols for policies
 - Change management process
 - Proposal accepted; procedure being written
 - Format of policies
 - Proposal accepted; will be included in site Document Control System.
- Create New Policy Manual
 - Late: Plan changed to have OQBP to work with MSOs or their representatives as of 03/15/11
 - Started with Operations policy; initial draft is in review



- Contractor Assurance System Description
 - Determine CAS Description Approach
 - Complete: had to be redone based upon FRA Steering Committee input.
 - Create Document
 - Late: draft being modified after FSO review.
- Revise Fermilab Contractor Assurance Program document
 - Late: partial editing complete; awaiting Contractor Assurance Description to ensure no changes.
 - Final draft is in review with FRA and will be provided to DOE within a few days.



- Management Review Procedure
 - Draft Management Review Procedure
 - Establish Board of Directors (BoD) role
 - Reporting and Metrics
 - Establish reporting methods to the BoD
 - Establish metrics for management systems
 - Late: initial draft ready for review, but is awaiting Contractor Assurance Description to ensure no changes.



- ♦ Formalize worker feedback system; create documentation TBD
 - Note Proposal is to perform an As-Is or survey on this topic and then, write the document(s).
- Consolidated/comprehensive Assessment
 - See Quality Implementation
- Communicate CAS to Fermilab
 - FRA, Fermilab senior management, and AC meetings On-going.
 - Training plan Fermilab
 - FRA One person trained
 - FSO Complete
 - Lab-wide Awareness Need to define SOW and create materials



- Benchmarking
 - Establish Benchmarking Requirements
 - Write Benchmarking Procedure
 - Create Implementation Plan
 - Late: not started
- Enterprise Risk Management/Graded Approach
 - Determine Graded Approach Methodology
 - Late: proposal awaiting review
 - Write Procedure
 - Create Implementation Plan



OPPS - OQBP Status Update

Contractor Assurance Short Term Upcoming Events



Contractor Assurance Short Term Upcoming Events

♦ FRA CAS Steering Committee Assessment

June '11

♦ DOE Peer Review of Contractor Assurance Program August '11



CA Implementation

Questions?

